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| 10/501,247 | 07/12/2004 | Detlev Neuland | 01/090LTS | 5234 |
| Propat 425-C South Sharon Amity Road Charlotte, NC 28211-2841 | | | EXAMINER HELM, CARALYNNE E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/501,247

Applicant(s)

NEULAND ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1, 3 and 5-10 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1, 3, and 5-10 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-SB-03)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Status of the Appeal

In view of the appeal brief filed on November 14, 2011, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Specification

The disclosure is objected to because of the following informalities: line 14 of page 2 contains the abbreviation "i.a." and line 25 on the same page includes the abbreviation "a.m." Neither of these two abbreviations are defined, therefore their meaning is unknown.

Appropriate correction is required.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities: Claim 1 recites "after-burning using controlled air circulation" which should read "after-burner using controlled air circulation". Claims 1 and 3 both recite a listing of composite materials for the carrier that includes an extra "or" ("a composite material composed of paper, polymer or a thin metal foil or polymer and a thin metal foil").

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for uncoated paper carriers, does not reasonably provide enablement for carriers composed of the broad genus of carrier materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

[In re Sichert, 196 USPQ 209 (CCPA 1977)]

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping

that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level:

The invention relates to methods of removing diffusion contaminants from a carrier material previous employed as a casting substrate for a drug, food, or cosmetic film. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. Here a carrier material must be employed that is susceptible to diffusion of substances found in the coating. The applicants highlight drugs as particular contaminating substances of interest as well as particular materials that are envisioned as the carrier (see instant specification page 2 lines 19-26 and page 2 line 28-page 3 line 5). The envisioned films employed for the carrier that are also embraced by the claims were composed of paper, thin metal foil, polyethylene, polyvinylchloride, polyvinylidenechloride, polyesters, or siliconized paper where this last variety is preferred. As a fibrous, porous material, an uncoated paper film would be susceptible to diffusion of drug; however, most of the envisioned carrier materials are not. Panoz teaches that aluminum foil is impermeable to drug (see US Patent No. 4,592,753 – column 4 lines 54-56 and 58-60). Theeuwes et al. teach partition materials for impermeable barriers in a drug delivery device and name high density polyethylene, polypropylene as well as polyethylene coated foil as envisioned barriers for this purpose (see US Patent No. 4,455,143 - column 7 lines 7-12, 14-18,

and 53-57). Fisher et al. teach a film of polyethylene or polypropylene as a drug impermeable barrier on a drug delivery system (see column 5 lines 6-8). Berner et al. (US Patent No. 5,064,654) teach a transdermal device composed of a reservoir formed between a permeable membrane and impermeable backing layer that is impermeable to ethanol drug and water (see column 3 lines 28-31). This impermeable material is envisioned as high, medium, or low density polyethylene, polypropylene, polyvinylchloride as well as polyvinylidene chloride (see column 7 lines 36-40 and 45-48). In addition, Solomon et al. teach that siliconized paper is naturally impermeable to drugs (see US PGPub No. 2005/0287195 - paragraph 52). Consequently, most of the particular envisioned carrier materials, which includes the most preferred carrier, are not susceptible to diffusion by drug since the prior art identified them as being impermeable to drugs. Although the instant disclosure notes that the temperature and time for thermal exposure sufficient to remove essentially all of the contaminant can be determined by conventional means, there is no guidance as to the nature of these conventional means or if they can also be used to predict whether a material is susceptible to diffusion by substances in the removed film composition. Therefore it is not predictable whether the contaminant of most concern in the disclosure or any other ingredient of the film would be able to diffusion into a carrier of the invention

2. The breadth of the claims:

The claims recite contamination of the carrier by a "substance" in the coating that is applied to and peeled from the carrier. Thus every ingredient included in a coating composition is a candidate for contaminating the carrier. Additionally, the carriers that become contaminated are not limited. Further, the amount of material that must be removed is broadly recited as is the temperature and duration of thermal exposure employed to achieve the removal.

3. The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples in the disclosure. In addition, there is insufficient guidance provided such that the artisan would be able to predict which carrier materials would be susceptible to diffusion and thus fall within the bounds of the invention because the most preferred carrier and most of those named are outside the invention.

4. The quantity of experimentation necessary

In order the practice the invention, the artisan would be required to perform a host of experiments which would present an undue burden. Since applicants have provided no guidance concerning testing methodologies, the artisan would have to seek out a testing scheme that would be sufficiently sensitive to accurately measure the presence of diffusion products in a film as well as the rate of any diffusion that occurs. In addition, the artisan would have to determine if the time scale over which any assessed

diffusion occurred was relevant to the coating method (e.g. would the contaminant be in contact with the carrier long enough during the coating process to diffuse into the carrier). The artisan would also have to develop some way to determine if the assessment was representative of the exposure conditions (e.g. substance concentration, exposure temperature, etc.). These experiments would have to be conducted with every combination of carrier and ingredient in the coating composition. If any combination was found to be susceptible to diffusion over the coating period, it would then have to be assessed to determine if the substance could then be removed within approximately 0.5 to 6 minutes at approximately 80°C via assessment techniques that the applicants have not disclosed. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Response to Arguments

The applicants' arguments, filed November 14, 2011, have been fully considered and are persuasive concerning the lack of recognition by the cited prior art of diffusion contamination of carriers employed in film casting production lines. Therefore, all previous grounds of rejection have been withdrawn. However, upon further consideration, a new ground of rejection is made which has been detailed in the preceding section.

Allowable Subject Matter

The prior art recognized a desire to clean carrier belts that are employed for the production of cast polymer matrices (e.g., films). A variety of techniques, which include thermal treatment, were taught for this end. Carrier materials envisioned and recited by the instant claims are taught in the prior art and the desire to clean these materials was also recognized. However, the art did not highlight the mechanism by which contamination occurs. Thus the recognition of contamination by diffusion is not discussed in the prior art. As a carrier material known for use in film casting process lines that would also be susceptible to diffusion of coating materials due to its porous nature, the instant method where uncoated paper is the carrier would be enabled and free of the art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615